

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Atty. Sana Pratt on 2/5/09.

The application has been amended as follows:

#### IN THE CLAIMS:

4. (Currently amended) A purified recombinant polypeptide LSA-NRC(H) specified in SEQ ID NO:26.

24. (Currently amended) A method for producing and purifying recombinant *P. falciparum* LSA-NRC(H) polypeptide of claim 4 comprising:

- (i) growing a host cell containing a vector expressing *P. falciparum* LSA-NRC(H) polypeptide of claim 4 in a suitable culture medium,
- (ii) causing expression of said vector under suitable conditions for production of soluble LSA-NRC(H) polypeptide and,
- (iii) lysing said host cells and recovering said LSA-NRC(H) polypeptide such that it retains its native folding.

26. (Currently amended) The method of claim 25 wherein said removal of endotoxin is by

(i) application of the lysed bacteria to a resin containing Ni-NTA and washing said resin bound material with low pH, high salt buffer,

(ii) removal of bound material from Ni-NTA resin and binding to other ion affinity resins such as DEAE and SP-Sepharose resins such that the LSA-NRC(H) polypeptide binds and the endotoxins can be washed away.

39. (Currently amended) The ~~[[A]]~~ purified recombinant protein according to claim 4, wherein said purified recombinant protein is at least 90% pure.

45. (Currently amended) A method for *in vitro* diagnosis of malaria antibodies in a biological sample, comprising

(i) contacting said biological sample with a composition comprising a LSA-NRC(H) polypeptide according to claim 4 [[1]] under appropriate conditions which allow the formation of an immune complex, wherein said polypeptide ~~peptide~~ is labeled with a detectable label, and

(ii) detecting the presence of said immune complexes visually or mechanically.

46. (Currently amended) A kit for determining the presence of malaria antibodies in a biological sample, comprising:

(i) ~~at least one polypeptide or a~~ polypeptide protein composition according to claim 9, a buffer or components necessary for producing a buffer;

(ii) means for detecting immune complexes between the polypeptide ~~peptide~~ and antibodies present in the sample.

49. (Currently amended) A kit for monitoring malaria infection or prognosing the response to treatment of patients suffering from malaria infection comprising:

- (i) at least one LSA-NRC(H) polypeptide ~~peptide~~ according to claim 4,
- (ii) a buffer or buffer components,
- (iii) means for detecting the immune complexes formed between the polypeptide ~~peptide~~ and antibodies present in the sample, ~~and~~
- (iv) ~~optionally, a means for determining the amount of immune complex formed.~~

74. (Currently amended) A method for inducing in a subject an immune response against malaria infection comprising administering to said subject a composition comprising an immunologically effect amount of *P. falciparum* LSA-NRC(H) of claim 4 in an acceptable diluent.

Claims 5, 10-23, 27-38, 43, 47, 48, 53, 58, 63, 65-73, 77-85, 88-90 are cancelled.

Claims 4, 9, 39, 42, 46, 49, 52, 57, 62, 74-76, 93 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 24- 26, 45, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 6/16/06 is hereby withdrawn.** In view of the withdrawal of the restriction

requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 4, 9, 24-26, 39, 42, 45-46, 49, 52, 57, 62, 93 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

NV  
2/4/09